UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,099	07/31/2006	Paul Gregor	2819.002	4261

23405 7590 06/18/2008

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,099	GREGOR ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed on 6/28/05, is acknowledged.

2. Claims 1-35 are pending and being acted upon presently

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-12, drawn to a method of screening for small orgainic compound that inhibits the interaction of GAGs with GAG specific ECAMs.

II. Claims 13-18, drawn to a composition obtained from a method of screening.

III. Claims 19-27, drawn to a method for inhibiting cell adhesion or cell migration comprising the step of exposing a cell to a small organic compound which interacts with at least one GAG in an amount sufficient for preventing the interactions of the GAG with at least one GAG specific ECAM.

IV. Claims 28-29, drawn to a method for modulating anticoagulant activity of glycosaminoglycans in a subject comprising the step of administering a therapeutically effective amount of a pharmaceutical composition obtained in a method of screening thereby modulating the anticoagulant activity of glycosaminoglycans.

V. Claims 30-32, drawn to a method for the treatment or prevention of a condition, process, or a disorder related to cell adhesion or migration in a subject comprising administering a composition comprising an active ingredient of a small organic compound that inhibits the interaction of at least one GAG with at least one GAG specific ECAM, thereby preventing cell adhesion or cell migration mediated by the GAG, wherein the process, condition or disorder related to cell adhesion or migration is inflammatory processes.

VI. Claims 30 and 33, drawn to a method for the treatment or prevention of a condition, process, or a disorder related to cell adhesion or migration in a subject comprising administering a composition comprising an active ingredient of a small organic compound that inhibits the interaction of at least one GAG with at least one GAG

specific ECAM, thereby preventing cell adhesion or cell migration mediated by the GAG, wherein the process, condition or disorder related to cell adhesion or migration is autoimmune processes.

VII. Claims 30 and 34, drawn to a method for the treatment or prevention of a condition, process, or a disorder related to cell adhesion or migration in a subject comprising administering a composition comprising an active ingredient of a small organic compound that inhibits the interaction of at least one GAG with at least one GAG specific ECAM, thereby preventing cell adhesion or cell migration mediated by the GAG, wherein the process, condition or disorder related to cell adhesion or migration is cancer or cancer metastasis.

VIII. Claims 30 and 31, drawn to a method for the treatment or prevention of a condition, process, or a disorder related to cell adhesion or migration in a subject comprising administering a composition comprising an active ingredient of a small organic compound that inhibits the interaction of at least one GAG with at least one GAG specific ECAM, thereby preventing cell adhesion or cell migration mediated by the GAG, wherein the process, condition or disorder related to cell adhesion or migration is atherosclerosis.

IX. Claims 30-31 and 35, drawn to a method for the treatment or prevention of a condition, process, or a disorder related to cell adhesion or migration in a subject comprising administering a composition comprising an active ingredient of a small organic compound that inhibits the interaction of at least one GAG with at least one GAG specific ECAM, thereby preventing cell adhesion or cell migration mediated by the GAG, wherein the process, condition or disorder related to cell adhesion or migration is bone degradation, restenosis, eczema, osteoporosis and osteoarthritis or wound healing.

4. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Diamond et al, J. Cell Biol., 1995 (see entire document).

Diamond et al teach that they demonstrate a direct interaction between Mac-1 (GAG specific ECAM) and heparan sulfate glycans (GAG). Heparin affinity resins immunoprecipitate Mac-1, and neutrophils and transfectant cells that express Mac-1 (GAG specific ECAM) bind to heparin and heparan sulfate (GAG), but not to other sulfated glycosaminoglycans inhibition. Studies (screening/identifying) with mAbs and chemically modified forms of heparin (small organic molecule) suggest the I domain as a recognition site on Mac-1 for heparin, and suggest that either N- or O-sulfation is sufficient for heparin to bind efficiently to Mac-1(the abstract).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If anyone Group I-IV is elected, applicant is required to elect a single specific GAG such as the one recited in claim 3-6 and a single specific GAG specific ECAM such as the one recited in claim 7-8. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If Group V is elected, applicant is required to elect a single specific inflammatory process such as the one recited in claim 32. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

C. If Group VI is elected, applicant is required to elect a single specific inflammatory autoimmune process such as the one recited in claim 33. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

D. If Group IX is elected, applicant is required to elect a single specific disease such as the one recited in claim 35. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 9, 2008

/Maher M. Haddad/
Primary Examiner,
Art Unit 1644